

ABSTRACT OF THE DISCLOSURE

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5 An article and a method for monitoring the concentration of glucose in blood. In one aspect, the invention involves an article comprising a multiple-layer element utilizing reagents capable of reacting with an analyte of interest. In a preferred embodiment, the element comprises:

- 10 (a) a core layer having two major surfaces, an optical reading chamber extending from a first opening in one of said two major surfaces to a second opening in the other of said two major surfaces, said core layer further having a third opening therein and a flow channel, one end of which flow channel communicates with the third opening and the other end of which flow channel communicates with the optical reading chamber; and
- 15 (b) a base layer in face-to-face contact with one major surface of said core layer; and
- (c) a cover layer in face-to-face contact with the other major surface of said core layer, said cover layer having an opening therein to vent the element..

20 In this embodiment, the optical reading chamber extends completely through the core layer. The sample is introduced into the third opening and then flows through the flow channel into the optical reading chamber. The reagents with which the analyte in the sample reacts to form an optically detectable reaction product can be disposed in the optical reading chamber or can be added to the sample before the sample enters the optical reading chamber. In another aspect, the invention involves a method

25 comprising the steps of:

- (a) obtaining a sample of biological fluid, e. g., interstitial fluid, from the body of a patient;
- 30 (b) introducing the sample to article comprising a multiple-layer element having an optical reading chamber;
- (c) allowing reagents to react with an analyte of interest in the sample; and
- (d) measuring the concentration of analyte in the sample by means of an optical instrument.